STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State WASHINGTON

STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES

The Consolidated Omnibus Budget Reconciliation Act of 1985 (signed by the President April 7, 1986) requires written standards for the provision of organ transplants. State Plans must provide for standards that treat similarly situated individuals alike, identify restrictions on the facilities or practitioners providing organ transplantation procedures, and are consistent with the accessibility of high quality care to those individuals eligible for the procedures under the State Plan. Heart-lung, lung, pancreas-kidney, pancreas, heart, liver and bone marrow transplants (in addition to cornea and kidney) are medically necessary and reasonable when patient selection criteria are observed and when performed at a facility that meets certain criteria. Compound transplants of three or more organs are viewed as experimental.

STANDARDS

I. Patient Selection

Policy Statement. In general, the Medical Assistance recipient must have end stage organ disease, a poor prognosis (for example, in the case of heart disease, less than 25 percent likelihood of survival for six months or more) as a result of poor organ functional status; .the pancreas is an exception to this. All other medical and surgical therapies that might be expected to yield both short- and long-term survival (for example, three to five years) comparable to that of organ transplantation must have been tried or considered. Standards are designed to ensure that patients are selected so that organ transplantation as a therapy will have a successful clinical outcome.

Factors to be considered in the patient selection process include the following conditions:

1. Advancing age (the selection of a recipient for [not pancreas] transplantation beyond age 60 must be done with particular care to ensure an adequately young "physiologic" age and the absence or insignificance of coexisting disease); beyond age 40 for pancreas transplants will be reviewed with special care.

2. Severe pulmonary hypertension (because of the limited work capacity of the typical donor's right ventricle in case of heart transplantation).

3. Other organ dysfunction; e.g., renal or hepatic in the case of cardiac transplantation not explained by the underlying heart failure; (where multiple organ transplant is not proposed and/or will not solve this problem).

4. Acute, severe hemodynamic compromise at the time of transplantation if accompanied by compromise or failure of a vital end organ.

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5. Symptomatic peripheral or cerebrovascular disease; is an absolute contraindication to participation in all transplants.

6. Chronic obstructive pulmonary disease or chronic bronchitis.

7. Active systemic infection.

8. Recent or unresolved pulmonary infarction or x-ray evidence of infection or of abnormalities of unclear etiology.

9. Systemic hypertension that requires multi-drug therapy for control; an exception may be considered in renal transplants.

10. Other systemic disease considered likely to limit or preclude survival and rehabilitation after transplantation.

11. Cachexia.

12. The need for prior transplantation of a second organ; i.e., lung, liver, kidney, heart or marrow (because this represents the coexistence of significant disease); exception pancreas after kidney.

13. A history of a behavior pattern or psychiatric illness considered likely to interfere significantly with compliance with a disciplined medical regimen (because a life long medical regimen is necessary, requiring multiple drugs several times a day, with serious consequences in the event of their interruption or excessive consumption).

13A. Noncompliance is the No. 1 cause of transplantation failure; patients with behavior patterns that may lead to interference must present evidence of compliance for one year and voluntary treatment program participation.

14. Other factors given less weight but still considered important include:

    a. Diabetes mellitus requiring insulin (because the diabetes is often accompanied by occult vascular disease and because the diabetes and its complications are exacerbated by chronic corticosteroid therapy); exceptions will be considered in combined pancreas/kidney in the young.

    b. Asymptomatic severe peripheral or cerebral vascular disease (because of accelerated progression in some patients after organ transplantation and chronic corticosteroid treatment).

    c. Peptic ulcer disease (because of the likelihood of early postoperative exacerbation); must be well controlled.

d. Current or recent history of unresected diverticulitis or other chronic infectious process (considered as a source of active infection which may be exacerbated with the initiation of an immunosuppressant).

The existence of one or more of these factors could lead to the disqualification of a Medical Assistance recipient as a candidate for organ transplantation.

II. Facilities and Practitioners

Organ transplantation procedures will be covered in centers approved by the Medical Director and on entering special agreements with the Division of Medical Assistance. Documentation that the center meets or exceeds these standards is required for approval.

1. The center has board certified/eligible practitioners in the fields of cardiology, hemodynamics and pulmonary function, cardiovascular surgery, anesthesiology, hepatology, hematology, immunology and infectious disease. Nursing, social services, and organ procurement services must complement the team. Specified team specific transplant coordinators are required for each organ.

2. The center has an active cardiovascular medical and surgical program with regard to heart transplants as evidenced by a minimum of 500 cardiac catherizations and coronary arteriograms and 250 open heart procedures per year.

3. The center has an anesthesia team that is available at all times.

4. The center has infectious disease services with both the professional skills and the laboratory resources that are needed to discover, identify, and manage a whole range of organisms.

5. The center has a nursing service team trained in the hemodynamic support of the patient and in managing immunosuppressed patients.

6. The center has pathology resources that are available for studying and reporting the pathological responses of transplantation.

7. The center has legal counsel familiar with transplantation laws and regulations.

8. Transplant surgeons and other responsible team members must be experienced, board certified or board eligible in their respective disciplines; organ specific transplant physicians are required for each organ/team.

9. Component teams must be integrated into a comprehensive transplant team with clearly defined leadership and responsibility.

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10. The center has social services resources.

11. The transplant center must safeguard the rights and privacy of patients.

12. The transplant center must have patient management plans and protocols.

13. The center participates in a donor procurement program and network (the National Organ Procurement and Transplantation Network - OPTN).

14. The center systematically collects and shares data on its transplant program.

15. The center has an interdisciplinary body to determine the suitability of candidates for transplantation on an equitable basis and submits its recommendation regarding Medical Assistance recipients to the Division of Medical Assistance.

15A. Recipient Selection

The center must have procedures in place and document selection of transplant candidates and distribution of organs in a fair and equitable manner conducive to optimal recipient outcome.

16. The center has extensive blood bank support.

17. The center must have an established organ transplantation program with documented evidence of 12 or more heart transplants, or 25 or more kidney transplants or 12 or more liver transplants annually. Centers within the state of Washington that fail to meet volume requirement may request conditional approval.

18. The center performing heart transplants must demonstrate actuarial survival rates of 73 percent for one year and 65 percent for two years or greater.

19. The center performing transplants must have UNOS approval - also concerning survival rate.

20. In-state centers granted conditional approval on an exception basis must meet criteria standards within one year.

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CRITERIA FOR PANCREAS TRANSPLANTATION
January 19, 1990

TRANSPLANT CRITERIA

A. PANCREAS TRANSPLANTATION

Indications:

1. Insulin-dependent diabetics with renal failure who will undergo a renal and pancreas transplant.

2. The insulin-dependent diabetic with prior kidney transplant to undergo a pancreas transplant.

3. The insulin-dependent diabetic with nonrenal complications, such as retinopathy, neuropathy, or early vascular changes, and those patients with poorly controlled diabetes who will undergo a pancreas-only transplant.

B. HEART - LUNG TRANSPLANT

Indications:

1. Primary Pulmonary Hypertension resulting from elevated pulmonary vascular resistance with poor survival prognosis for over 12 to 18 months.

2. Eisenmenger's Syndrome with same prognosis as above number 1.

3. Core Pulmonale with same prognosis as number 1.

4. Cystic Fibrosis with same prognosis as above number 1.

Contraindications:

1. Contraindications with the exception of pulmonary hypertension are otherwise the same as for heart transplant patients.

2. Given the scarcity of heart lung donors, priority will be given to patients under the age of 50.

3. Particular attention must be given in the selection of patients with previous thoracic surgery and patients with liver dysfunction as these factors significantly affect mortality in heart-lung transplantation:

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C. SINGLE LUNG TRANSPLANTATION

Indications:

1. Terminal restrictive lung disease with life expectancy less than 18 months.

2. Primary Pulmonary Hypertension.

3. Patient over the age of 60 must be selected with particular care because of the shortage of donor material.

4. Patients with severe obstructive lung disease (and air trapping) are not considered optimal candidates; this is considered a weak indication.

Contraindications:

1. Acute or chronic pulmonary infectious process.

2. Ventilator dependence.

3. Cachexia.

4. Severe right ventricular failure.

5. Multi-organ system failure.

6. Systemic disease that may affect long term graft function/survival and recipient survival.

7. The presence of a malignancy, or significant history thereof.

8. Severe obstructive lung disease where air trapping is a moderate contraindication.